K073231

APR 18 2008

510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92

Submitted by: LifeScan, Inc.
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Summary Date: November 14, 2007

Trade Name: OneTouch® UltraLink™ Blood Glucose Monitoring System

Common Name: Blood Glucose Monitor

Device Classification: Class II, Glucose Test System (21 CFR §862.1345, Product Code NBW)

Substantial Equivalence

The OneTouch® UltraLink™ Blood Glucose Monitoring System is substantially equivalent to the OneTouch® Ultra®2 Blood Glucose Monitoring System as cleared under K053529. Both devices have a similar intended use, measure the same sample type and have similar performance characteristics. The OneTouch® UltraLink™ Blood Glucose Monitoring System is substantially equivalent to the BD Paradigm Link® Blood Glucose Monitor as cleared under K040603 for the ability to transmit blood glucose results using Radio-Frequency telemetry.

Device Description

The OneTouch® UltraLink™ Blood Glucose Monitoring System is a modification to the OneTouch® Ultra® 2 Blood Glucose Monitoring System, retaining the features, functions, and user interface of the OneTouch® Ultra® 2 meter while introducing a feature allowing Radio-Frequency transmission of blood glucose results to compatible Medtronic MiniMed, Inc. devices. The OneTouch® UltraLink™ Blood Glucose Monitoring System is composed of the OneTouch®

UltraLink™ Blood Glucose meter, OneTouch® Ultra® Test Strips, OneTouch® Ultra® Control Solution, OneTouch® Lancing device, OneTouch® UltraSoft® Lancets, and meter carrying case. System modifications were made only to the blood glucose meter, carrying case, and instructions for use.

Intended Use

The OneTouch® UltraLink™ Blood Glucose Monitoring System is intended to be used for self-testing outside the body (*in vitro* diagnostic use) for the quantitative measurement of glucose in fresh capillary whole blood obtained from the finger, forearm or palm. The OneTouch® UltraLink™ System is intended for use by people with diabetes in a home setting and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

Technological Characteristics

Comparison with Predicate devices

Predicate Device	**Similarities to Subject Device**	**Differences between Subject Device (Modifications)**
OneTouch® Ultra®2 Blood Glucose Monitoring System (K053529) *Quantitative measurement of blood glucose*	Same intended use Same sample type Same fundamental scientific technology Same system components	Meter: ergonomic/physical design, electronic/hardware, software/firmware. Instructions for use – addition of Radio Frequency use information
BD Paradigm Link® Blood Glucose Monitor (K040603) *Radio-Frequency transmission of blood glucose results.*	Same fundamental scientific technology Equivalent radio-Frequency protocol specifications	RF module contained in a different blood glucose meter

Performance Summary

Performance Characteristic	Test method employed	Results
Precision	ISO 15197:2003, Section 7.2	The OneTouch® UltraLink™ Blood Glucose Monitoring System demonstrated acceptable system precision.
Accuracy	ISO 15197:2003 Section 7.3 (7.4)	Ninety-five percent (95 %) of the individual glucose results fell within ± 15 mg/dL of the results of the reference method at glucose concentrations < 75 mg/dL and within ± 20 % at glucose concentrations ≥75 mg/dL.
User Performance	ISO 15197:2003, Section 8	Results from performance and human factors studies at two U.S. clinical sites demonstrated equivalent ability of lay and professional users to obtain results suitable for the intended use of the device.
Linearity	CLSI/NCCLS EP-6A	The OneTouch® UltraLink™ Blood Glucose Monitoring System demonstrated acceptable system linearity over the measurement range.
Safety and Reliability	ISO 15197:2003, Section 6	The OneTouch® UltraLink™ Blood Glucose Monitoring System demonstrated acceptable safety and reliability per the test methods described.

Conclusion from Performance Evaluation

The OneTouch® UltraLink™ Blood Glucose Monitoring System demonstrates substantial equivalence to the OneTouch® Ultra®2 Blood Glucose Monitoring System, and to the BD Paradigm Link™ Blood Glucose Meter for the Radio-Frequency (wireless) communication feature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 18 2008

LifeScan, Inc.
c/o Ms. Kim Fonda
Regulatory Project Leader
1000 Gibraltar. Drive
Milpitas, CA 95035

Re: k073231
Trade/Device Name: One Touch Ultralink Blood Glucose Monitoring System
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: April 01, 2008
Received: April 02, 2008

Dear Ms. Fonda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K073231

Device Name: OneTouch® UltraLink™ Blood Glucose Monitoring System

Indications For Use:

The OneTouch® UltraLink™ Blood Glucose Monitoring System is intended to be used for self-testing outside the body (*in vitro* diagnostic use) for the quantitative measurement of glucose in fresh capillary whole blood obtained from the finger, forearm or palm. The OneTouch® UltraLink™ System is intended for use by people with diabetes in a home setting and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch® UltraLink™ Blood Glucose monitor may be used to transmit glucose values to appropriate MiniMed Paradigm® and Guardian® REAL Time devices using radio frequency communication.

Prescription Use _____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K073231